Potassium Hydroxide Phthalate Method,'' which is also incorporated by reference and available as set forth in paragraph (a)(4)(ii) of this section.

[44 FR 16235, Mar. 16, 1979, as amended at 47 FR 11822, Mar. 19, 1982; 49 FR 5609, Feb. 14, 1984; 54 FR 24892, June 12, 1989; 63 FR 14035, Mar. 24, 1998]

Subpart F—Records and Reports

§ 114.100 Records.

(a) Records shall be maintained of examinations of raw materials, packaging materials, and finished products, and of suppliers' guarantees or certifications that verify compliance with Food and Drug Administration regulations and guidance documents or action levels.

(b) Processing and production records showing adherence to scheduled processes, including records of pH measurements and other critical factors intended to ensure a safe product, shall be maintained and shall contain sufficient additional information such as product code, date, container size, and product, to permit a public health hazard evaluation of the processes applied to each lot, batch, or other portion of production.

(c) All departures from scheduled processes having a possible bearing on public health or the safety of the food shall be noted and the affected portion of the product identified; these departures shall be recorded and made the subject of a separate file (or log identifying the appropriate data) delineating them, the action taken to rectify them, and the disposition of the portion of the product involved.

(d) Records shall be maintained identifying initial distribution of the finished product to facilitate, when necessary, the segregation of specific food lots that may have become contaminated or otherwise unfit for their intended use.

(e) Copies of all records provided for in paragraphs (b), (c), and (d) of this section shall be retained at the processing plant or other reasonably accessible location for a period of 3 years from the date of manufacture.

[44 FR 16235, Mar. 16, 1979, as amended at 65 FR 56479, Sept. 19, 2000]

PART 115—SHELL EGGS

AUTHORITY: 21 U.S.C. 342, 371; 42 U.S.C. 243, 264, 271.

§ 115.50 Refrigeration of shell eggs held for retail distribution.

(a) For purposes of this section a ''retail establishment'' is an operation that stores, prepares, packages, serves, vends, or otherwise provides food for human consumption directly to consumers.

(b) Except as provided in paragraph (c) of this section, all shell eggs, whether in intrastate or interstate commerce, held for retail distribution:

(1) Shall promptly be placed under refrigeration as specified in paragraph (b)(2) of this section upon receipt at a retail establishment, except that, when short delays are unavoidable, the eggs shall be placed under refrigeration, as soon as reasonably possible; and

(2) Shall be stored and displayed under refrigeration at an ambient temperature not greater than 7.2 °C (45 °F) while held at a retail establishment.

(c) Shell eggs that have been specifically processed to destroy all viable *Salmonella* shall be exempt from the requirements of paragraph (b) of this section.

(d) Under sections 311 and 361 of the Public Health Service Act (PHS Act), any State or locality that is willing and able to assist the agency in the enforcement of paragraph (b) of this section, and is authorized to inspect or regulate retail establishments, may, in its own jurisdiction, enforce paragraph (b) of this section through inspections under paragraph (f) of this section and through administrative enforcement remedies identified in paragraph (e) of this section until FDA notifies the State or locality in writing that such assistance is no longer needed. When providing assistance under paragraph (e) of this section, a State or locality may follow the hearing procedures set out in paragraphs (e)(2)(iii) through (e)(2)(iv) of this section, substituting, where necessary, appropriate State or local officials for designated FDA officials or may utilize State or local hearing procedures if such procedures satisfy due process.

(e) This section is established under authority of both the Federal Food, Drug, and Cosmetic Act (the act) and the PHS Act. Under the act, the agency can enforce the food adulteration provisions under 21 U.S.C. 331, 332, 333, and 334. However, 42 U.S.C. 264 provides for the issuance of implementing enforcement regulations; therefore, FDA has established the following administrative enforcement procedures for the diversion or destruction of shell eggs and for informal hearings under the PHS Act:

(1) Upon finding that any shell eggs have been held in violation of this section, an authorized FDA representative or a State or local representative in accordance with paragraph (d) of this section may order such eggs to be diverted, under the supervision of said representative, for processing in accordance with the Egg Products Inspection Act (EPIA) (21 U.S.C. 1031 *et seq.*) or destroyed by or under the supervision of an officer or employee of the FDA, or, if applicable, of the State or locality in accordance with the following procedures:

(i) *Order for diversion or destruction.* Any district office of FDA or any State or local agency acting under paragraph (d) of this section, upon finding shell eggs held in violation of this section, may serve upon the person in whose possession such eggs are found a written order that such eggs be diverted, under the supervision of an officer or employee of the issuing entity, for processing in accordance with the EPIA (21 U.S.C. 1031 *et seq.*) or destroyed by or under the supervision of said district office, within 10-working days from the date of receipt of the order.

(ii) *Issuance of order.* The order shall include the following information:

(A) A statement that the shell eggs identified in the order are subject to diversion for processing in accordance with the EPIA or destruction;

(B) A detailed description of the facts that justify the issuance of the order;

(C) The location of the eggs;

(D) A statement that these eggs shall not be sold, distributed, or otherwise disposed of or moved except as provided in paragraph (e)(1)(v) of this section;

(E) Identification or description of the eggs;

(F) The order number;

(G) The date of the order;

(H) The text of this entire section;

(I) A statement that the order may be appealed by written appeal or by requesting an informal hearing;

(J) The name and phone number of the person issuing the order; and

(K) The location and telephone number of the office or agency and the name of its director.

(iii) *Approval of District Director.* An order, before issuance, shall be approved by the Food and Drug Administration (FDA) District Director in whose district the shell eggs are located. If prior written approval is not feasible, prior oral approval shall be obtained and confirmed by written memorandum as soon as possible.

(iv) *Labeling or marking of shell eggs under order.* An FDA, State, or local agency representative issuing an order under paragraph (e)(1) of this section shall label or mark the shell eggs with official tags that include the following information:

(A) A statement that the shell eggs are detained in accordance with regulations issued under section 361(a) of the PHS Act (42 U.S.C. 264(a)).

(B) A statement that the shell eggs shall not be sold, distributed or otherwise disposed of or moved except, after notifying the issuing entity in writing, to:

(*1*) Divert them for processing in accordance with the EPIA or destroy them; or

(*2*) Move them to an another location for holding pending appeal.

(C) A statement that the violation of the order or the removal or alteration of the tag is punishable by fine or imprisonment or both (section 368 of the PHS Act, 42 U.S.C. 271).

(D) The order number and the date of the order, and the name of the government representative who issued the order.

(v) *Sale or other disposition of shell eggs under order.* After service of the order, the person in possession of the shell eggs that are the subject of the order shall not sell, distribute, or otherwise dispose of or move any eggs subject to the order unless and until the notice is

withdrawn after an appeal except, after notifying FDA's district office or, if applicable, the State or local agency in writing, to:

(A) Divert or destroy them as specified in paragraph (e)(1)(i) of this section; or

(B) Move them to another location for holding pending appeal.

(2) The person on whom the order for diversion or destruction is served may either comply with the order or appeal the order to the FDA Regional Food and Drug Director in accordance with the following procedures:

(i) *Appeal of a detention order.* Any appeal shall be submitted in writing to FDA's District Director in whose district the shell eggs are located within 5-working days of the issuance of the order. If the appeal includes a request for an informal hearing, the hearing shall be held within 5-working days after the appeal is filed or, if requested by the appellant, at a later date, which shall not be later than 20-calendar days after the issuance of the order. The order may also be appealed within the same period of 5-working days by any other person having an ownership or proprietary interest in such shell eggs. The appellant of an order shall state the ownership or proprietary interest the appellant has in the shell eggs.

(ii) *Summary decision.* A request for a hearing may be denied, in whole or in part and at any time after a request for a hearing has been submitted, if the FDA Regional Food and Drug Director or his or her designee determines that no genuine and substantial issue of fact has been raised by the material submitted in connection with the hearing or from matters officially noticed. If the FDA Regional Food and Drug Director determines that a hearing is not justified, written notice of the determination will be given to the parties explaining the reason for denial.

(iii) *Informal hearing.* Appearance by any appellant at the hearing may be by mail or in person, with or without counsel. The informal hearing shall be conducted by the FDA Regional Food and Drug Director or his designee, and a written summary of the proceedings shall be prepared by the FDA Regional Food and Drug Director.

(A) The FDA Regional Food and Drug Director may direct that the hearing be conducted in any suitable manner permitted by law and this section. The FDA Regional Food and Drug Director has the power to take such actions and make such rulings as are necessary or appropriate to maintain order and to conduct an informal fair, expeditious, and impartial hearing, and to enforce the requirements concerning the conduct of hearings.

(B) Employees of FDA will first give a full and complete statement of the action which is the subject of the hearing, together with the information and reasons supporting it, and may present oral or written information relevant to the hearing. The party requesting the hearing may then present oral or written information relevant to the hearing. All parties may conduct reasonable examination of any person (except for the presiding officer and counsel for the parties) who makes any statement on the matter at the hearing.

(C) The hearing shall be informal in nature, and the rules of evidence do not apply. No motions or objections relating to the admissibility of information and views will be made or considered, but any party may comment upon or rebut any information and views presented by another party.

(D) The party requesting the hearing may have the hearing transcribed, at the party's expense, in which case a copy of the transcript is to be furnished to FDA. Any transcript of the hearing will be included with the FDA Regional Food and Drug Director's report of the hearing.

(E) The FDA Regional Food and Drug Director shall prepare a written report of the hearing. All written material presented at the hearing will be attached to the report. Whenever time permits, the FDA Regional Food and Drug Director may give the parties the opportunity to review and comment on the report of the hearing.

(F) The FDA Regional Food and Drug Director shall include as part of the report of the hearing a finding on the credibility of witnesses (other than expert witnesses) whenever credibility is a material issue, and shall include a recommended decision, with a statement of reasons.

(iv) *Written appeal.* If the appellant appeals the detention order but does not request a hearing, the FDA Regional Food and Drug Director shall render a decision on the appeal affirming or revoking the detention within 5-working days after the receipt of the appeal.

(v) *Regional Food and Drug Director decision.* If, based on the evidence presented at the hearing or by the appellant in a written appeal, the Regional Food and Drug Director finds that the shell eggs were held in violation of this section, he shall affirm the order that they be diverted, under the supervision of an officer or employee of the FDA for processing under the EPIA or destroyed by or under the supervision of an officer or employee of the FDA; otherwise, the Regional Food and Drug Director shall issue a written notice that the prior order is withdrawn. If the Regional Food and Drug Director affirms the order he shall order that the diversion or destruction be accomplished within 10-working days from the date of the issuance of his decision. The Regional Food and Drug Director's decision shall be accompanied by a statement of the reasons for the decision. The decision of the Regional Food and Drug Director shall constitute final agency action, reviewable in the courts.

(vi) *No appeal.* If there is no appeal of the order and the person in possession of the shell eggs that are subject to the order fails to divert or destroy them within 10-working days, or if the demand is affirmed by the Regional Food and Drug Director after an appeal and the person in possession of such eggs fails to divert or destroy them within 10-working days, FDA's district office or appropriate State or local agency may designate an officer or employee to divert or destroy such eggs. It shall be unlawful to prevent or to attempt to prevent such diversion or destruction of the shell eggs by the designated officer or employee.

(f) *Inspection.* Persons engaged in retail distribution of shell eggs shall permit authorized representatives of FDA to make at any reasonable time such inspection of the retail establishment in which shell eggs are being held, including inspection and sampling of such eggs and the equipment in which shell eggs are held and any records relating to such equipment or eggs, as may be necessary in the judgement of such representatives to determine compliance with the provisions of this section. Inspections may be made with or without notice and will ordinarily be made during regular business hours.

(g) *Preemption.* No State or local governing entity shall establish or continue in effect any law, rule, regulation, or other requirement allowing refrigeration of unpasteurized shell eggs at retail establishments at any temperature greater than 7.2 °C (45 °F).

[65 FR 76112, Dec. 5, 2000]

PART 119—DIETARY SUPPLEMENTS THAT PRESENT A SIGNIFICANT OR UNREASONABLE RISK

AUTHORITY: 21 U.S.C. 321, 342, 343, 371.

§ 119.1 Dietary supplements containing ephedrine alkaloids.

Dietary supplements containing ephedrine alkaloids present an unreasonable risk of illness or injury under conditions of use recommended or suggested in the labeling, or if no conditions of use are recommended or suggested in the labeling, under ordinary conditions of use. Therefore, dietary supplements containing ephedrine alkaloids are adulterated under section 402(f)(1)(A) of the Federal Food, Drug, and Cosmetic Act.

[69 FR 6853, Feb. 11, 2004]

PART 120—HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEMS

Subpart A—General Provisions

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